



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,799

08/06/2007

Rong Fan

DEX0499US.NP

2565

32800

7590

09/22/2009

LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

09/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,799	<b>Applicant(s)</b> FAN ET AL.	
	<b>Examiner</b> DAVID J. BLANCHARD	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 98 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8,11,13,15-17,21,22,27,28,30,50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/7/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>notice to comply seq.</u>              |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5,6,8,11,13,15-17,21,22,24,26-28,30,34-36,39,40,43,44,48-52,56,58,62,67,68 and 71.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 24, 26, 34-36, 39-40, 43-44, 48-49, 52, 56, 58, 62, 67-68n and 71.

**DETAILED ACTION**

1. The preliminary amendment filed 21 September 2006 has been entered in full.
2. Claims 3-4, 7, 9-10, 12, 14, 18-20, 23, 25, 29, 31-33, 37-38, 41-42, 45-47, 53-55, 57, 59-61, 63-66, 69-70 and 72-76 are cancelled.
3. Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 24, 26-28, 30, 34-36, 39-40, 43-44, 48-52, 56, 58, 62, 67-68 and 71 are pending.

***Election/Restrictions***

4 Applicant's election with traverse of the invention of Group I, claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 in the reply filed on 08 June 2009 is acknowledged. The traversal is on the grounds that Keolsch et al (WO 98/22597, 5/28/1998, IDS filed 12/7/2006) do not teach or suggest any deposited hybridomas or antibodies produced thereby, instead Keolsch et al provides general teachings of antibody production without any specific examples of antibodies being produced. Accordingly, Keolsch et al are in no way enabling for the instantly claimed invention and therefore cannot anticipate the special technical feature of the instant invention. This has been fully considered but is not found persuasive. As set forth in the restriction requirement mailed 5/6/09, Keolsch et al teach antibodies that bind napsin A, which as evidenced by the specification at page 11, lines 23-24 is identical to Lng105. To the extent that applicant is arguing that one skilled in the art could not produce antibodies, Keolsch et al teach that polyclonal and monoclonal antibodies could be produced by standard techniques (page 11). Applicant is reminded that when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. Further, applicant is reminded that a prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax*

Art Unit: 1643

*Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006).

To the extent that applicant is arguing that Keolsch et al do not teach any specific antibodies to napsin A or epitopes thereof and it is unknown whether the antibodies taught by Keolsch would compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629, it is reiterated that Keolsch et al teach polyclonal and monoclonal antibodies that bind napsin A (identical to Lng105) and hence, one of ordinary skill in the art would reasonably conclude that the Keolsch et al antibodies, *particularly the polyclonal antibodies, which are polyreactive*, also possess the same structural and functional properties as those of the antibodies claimed (i.e., would compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629) and, therefore, it appears that Keolsch et al have produced antibodies that are identical to the claimed antibodies. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). In view of the teachings of Keolsch et al. the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 24, 26, 34-36, 39-40, 43-44, 48-49, 52, 56, 58, 62, 67-68 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Art Unit: 1643

6. Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 are under consideration.

***Sequence Requirements***

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. The specification at page 88, lines 6-7 contain sequences that are encompassed by the sequences rules and require sequence identifiers (SEQ ID numbers). Applicants' cooperation is requested in reviewing the entire disclosure to ensure that the application is in sequence compliance.

8. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attached).

9. APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Direct the response to the undersigned.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1643

11. Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description.

It is unclear if a cell line, which produces an antibody having the exact chemical identity of the antibodies produced by the hybridomas of PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629 is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

For example, very different  $V_H$  chains (about 50% homologous) can combine with the same  $V_K$  chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different  $V_H$  sequences combine with different  $V_K$  sequences to produce antibodies with very similar properties. The results indicate that divergent variable region sequences, both in and out of the complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. Paul, William E., *Fundamental Immunology*, 3rd Edition, Raven Press, New York, Chapt. 8, pg. 242 (1993). Therefore, it would require undue experimentation to reproduce the claimed antibody species, i.e., the antibodies produced by the hybridomas of PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629.

The specification lacks complete deposit information for the deposit of anti-Lng105 antibodies PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629. It is unclear whether antibodies possessing the identical properties of anti-Lng105 antibodies

Art Unit: 1643

PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a cell line is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed hybridoma cell lines and monoclonal antibodies, this method will not necessarily reproduce antibodies and hybridomas which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive a monoclonal antibody and hybridoma identical to those claimed. Undue experimentation would be required to screen all of the possible antibody and hybridoma species to obtain the claimed antibodies and hybridomas.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed antibodies PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629, a suitable deposit is required for patent purposes, evidence of public availability of the claimed antibody or evidence of the reproducibility without undue experimentation of the claimed antibody, is required.

Applicant's referral to the deposit of antibodies PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629 on page 102 of the specification is an insufficient assurance that the required deposit has been made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit of antibodies PTA-5878, PTA-5879, PTA-6146, PTA6147 and PTA-6629 has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.



Art Unit: 1643

If the deposit of antibodies PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629 is not made under the provisions of the Budapest Treaty, then in order to certify that the deposit complies with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

- (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
- (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
- (c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
- (d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States (e.g., deposit of PTA-6146, PTA-6147 and PTA-6629), a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed. See MPEP 2406 and 37 CFR 1.804(b).

Art Unit: 1643

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 5-6, 8, 11, 15-17 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Keolsch et al (WO 98/22597, 5/28/1998, IDS filed 12/7/2006).

Keolsch et al teach antibodies, including humanized antibodies that bind the aspartic protease napsin A, which as evidenced by the specification at page 11, lines 23-24 is identical to Lng105, wherein aspartic proteases are well known to be correlated with disorders such as breast cancer and the antibodies are produced by immunization with napsin A and the antibodies may be labeled with radiolabels, fluorescent labels, or chemiluminescent labels for immunodetection (see entire document, particularly pp. 8-12 and 15). Therefore, it is the examiner's position that the antibodies of Keolsch et al would compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629 and would necessarily have the recited binding properties of claims 6, 15-17 and 21-22. One of ordinary skill in the art would reasonably conclude that the Keolsch et al antibodies also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Keolsch et al have produced antibodies that are identical to the claimed antibodies. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibodies with the antibodies of Keolsch et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibodies and the antibodies of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keolsch et al (WO 98/22597, 5/28/1998, IDS filed 12/7/2006) in view of Devaux et al (U.S. Patent 6,824,780 B1, priority to 10/29/1999).

Keolsch et al have been described supra. Keolsch et al do not teach wherein the antibodies conjugated to a cytotoxic agent, a toxin, ricin, saponin, maytansinoid and calicheamicin or compositions comprising the antibody or conjugates thereof and a carrier, or articles of manufacture comprising a container comprising a composition

Art Unit: 1643

comprising the antibody and further comprising a package insert indicating that the composition can be used to diagnose, image or treat lung or breast cancer. These deficiencies are made up for in the teachings of Devaux et al.

Devaux et al teach antibodies that bind a cancer antigen for immunodetection and immunotherapy of cancer, wherein the antibodies include chimeric and humanized antibodies and are conjugated to therapeutic moieties including growth inhibitory agents, a cytotoxic agent, a toxin including ricin, saponin, a maytansinoid and calicheamicins and Devaux et al teach compositions comprising the antibody and a pharmaceutically acceptable carrier or excipient as well as articles of manufacture or kits comprising a container comprising the antibody compositions and a label or package insert (see entire document, particularly cols. 8, 10, 16-17, 23-24, 31-34, 42-43 and 47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced anti-napsin A antibodies including humanized antibodies wherein the antibodies are conjugated to an imaging agent, or a cytotoxic agent, a toxin, ricin, saponin, a maytansinoid or calicheamicin as well as compositions comprising the antibody or conjugates thereof and a pharmaceutically acceptable carrier or excipient and articles of manufacture or kits comprising a container comprising the antibody compositions and a label or package insert for therapeutic benefit in breast cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced anti-napsin A antibodies including humanized antibodies wherein the antibodies are conjugated to an imaging agent, or a cytotoxic agent, a toxin, ricin, saponin, a maytansinoid or calicheamicin as well as compositions comprising the antibody or conjugates thereof and a pharmaceutically acceptable carrier or excipient and articles of manufacture or kits comprising a container comprising the antibody compositions and a label or package insert for therapeutic benefit in breast cancer patients in view of Keolsch et al and Devaux et al because Keolsch et al teach antibodies, including humanized antibodies that bind the aspartic protease napsin A, which as evidenced by the specification at page 11, lines 23-24 is identical to Lng105, wherein aspartic proteases are well known to be correlated with

Art Unit: 1643

disorders such as breast cancer and the antibodies are produced by immunization with napsin A and the antibodies may be labeled with radiolabels, fluorescent labels, and chemiluminescent labels for immunodetection and Devaux et al teach antibodies that bind a cancer antigen for immunodetection and immunotherapy of cancer, wherein the antibodies include chimeric and humanized antibodies and are conjugated to therapeutic moieties including growth inhibitory agents, a cytotoxic agent, a toxin including ricin, saponin, a maytansinoid and calicheamicins and Devaux et al teach compositions comprising the antibody and a pharmaceutically acceptable carrier or excipient as well as articles of manufacture or kits comprising a container comprising the antibody compositions and a label or package insert. Therefore, one of ordinary skill in the art would have been motivated to have conjugated the anti-napsin A antibodies of Keolsch et al to the therapeutic moieties as taught by Devaux et al and produced compositions and articles of manufacture comprising such for therapeutic benefit in breast cancer patients. Thus, it would have been *prima facie* obvious to one skilled in the art to have produced anti-napsin A antibodies including humanized antibodies wherein the antibodies are conjugated to an imaging agent, or a cytotoxic agent, a toxin, ricin, saponin, a maytansinoid or calicheamicin as well as compositions comprising the antibody or conjugates thereof and a pharmaceutically acceptable carrier or excipient and articles of manufacture or a kit comprising a container comprising the antibody compositions and a label or package insert for therapeutic benefit in breast cancer patients in view of Keolsch et al and Devaux et al.

Since Keolsch et al teach antibodies against napsin A, which is identical to the instantly claimed Lng105 antigen as evidenced by the specification at page 11, lines 23-24, it is the examiner's position that the antibodies and antibody conjugates thereof of Keolsch et al and Devaux et al would necessarily compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629. One of ordinary skill in the art would reasonably conclude that antibodies and antibody conjugates of Keolsch et al and Devaux et al also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Keolsch et al and Devaux et al have produced antibodies

Art Unit: 1643

and antibody conjugates that are identical to the claimed antibodies and antibody conjugates. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibodies and antibody conjugates with the antibodies and antibody conjugates of Keolsch et al and Devaux et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibodies and antibody conjugates and the antibodies and antibody conjugates of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/  
Primary Examiner, A.U. 1643